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BY Victoria A. Jones

DATE: 10/23/02

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**RECEIVED**

In Re: Patent Application of : Group Art Unit: 1644  
Peter Watts, *et al.* :  
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Conf. No.: 9982 :  
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Appln. No.: 09/848,600 : Examiner: Phillip Gambel  
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Filed: May 3, 2001 :  
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Title: DRUG DELIVERY :  
COMPOSITION FOR THE : Attorney Docket  
NASAL ADMINISTRATION : No.: 10774-23U1  
OF ANTIVIRAL AGENTS : (WESZ/P14288US)

OCT 30 2002

TECH CENTER 1600/290

**RESPONSE TO RESTRICTION REQUIREMENT**

This response is provided in reply to the Restriction Requirement mailed September 23, 2002. It is timely filed on October 23, 2002.

Claims 1-5, 7, and 9-12 are pending in this application.

In Paper No. 8, the Examiner has imposed a Restriction Requirement between Groups I and II as defined below:

- (a) Group I (claims 1-5, 7, and 9-11), drawn to a drug delivery composition comprising ICAM-1 and a bioadhesive, classified in class 514, subclass 8; and
- (b) Group II (claim 12), drawn to methods of delivering ICAM-1 to the nasal passage, classified in class 424, subclass 184.1.

As basis for the imposition of the restriction requirement, the Examiner asserts that, although the inventions of Groups I and II are related as product and processes of use, the inventions are distinct as the claimed product can be used in a materially different process. The Examiner suggests that the claimed product can be used in "affinity purification" and "in vitro bioassays." Further, the Examiner argues that the compositions comprising ICAM-1 and materials other than bioadhesives can be employed to deliver ICAM-1 to the nasal passage. The applicants respectfully traverse the imposition of this Restriction Requirement.

The Examiner states that the product as claimed can be used in materially

different processes and suggests "affinity purification" and "in vitro bioassays". The applicants disagree. The composition is a drug delivery composition comprising ICAM-1 and a bioadhesive material, a material that adheres to the epithelial surface or to mucous overlying the epithelial surface of the nasal mucosa, by chemical or physical binding, including binding by vanderwalls interactions, ionic interactions, hydrogen bonding, or by polymer chain entanglement. Accordingly, such bioadhesive materials are likely capable of binding to any other components present in the solution which is being subjected to "affinity purification", or of binding to the component that is being assayed in the Examiner's proposed "in vitro assay." Thus, the applicants submit that a person of ordinary skill could not successfully use the composition of the invention in affinity purification or assays. Because the Examiner has failed to provide logical reasons with sound technical basis for the alleged "distinctiveness" of Group I and Group II, the requirement of restriction is improper.

For at least the reasons set forth above, it is respectfully requested that the Examiner reconsider and withdraw the imposition of the Restriction Requirement.

#### **PROVISIONAL ELECTION**

In the event that the Examiner does not withdraw the Restriction Requirement, the applicants hereby provisionally elect for prosecution claims of Group I (claims 1-5, 7, and 9-11). The applicants make such election without prejudice to the filing of a subsequent continuing application containing non-elected subject matter.

Respectfully submitted,

**PETER WATTS, et al.**

23 october 2002  
(Date)

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